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Methods for providing expiratory pressure relief in positive airway pressure therapy

Introduction

Patients receiving CPAP therapy not infrequently complain of difficulty in exhaling, particularly at higher CPAP pressures. The work of breathing is increased by CPAP. The expiratory reserve volume during CPAP is higher than when CPAP is not present, which is unpleasant for many. Subjectively it is hard to breathe out, though easy to breathe in. To alleviate these problems, it is desirable to provide a pressure waveform which makes exhalation easier and decreases the work of breathing. A variety of methods exist for this purpose, including bilevel ventilation.

In bilevel ventilation, there are typically delays in detecting the onset of inspiration and then in delivering the desired increase in pressure to the inspiratory level. As a special case, suppose that a certain mask pressure is necessary to prevent upper airway obstruction at peak inspiratory flow, and the bilevel inspiratory pressure (IPAP) is set to equal this pressure. Then because of the abovementioned delays, it may be the case that the pressure delivered is less than IPAP at the time of peak inspiratory flow, resulting in upper airway obstruction. More generally, the pressure required to prevent upper airway obstruction varies during the respiratory cycle, and the delay in delivering IPAP may result in a pressure below that required to prevent obstruction, more probably earlier in inspiration than the time of peak inspiratory flow, when the difference between the actual pressure and that required to prevent obstruction is larger.

In order to prevent this, it may be necessary to set IPAP to a level somewhat above the pressure required to prevent obstruction at peak inspiratory flow (which is probably the optimum level), and it is not easy to determine how high this pressure should be. In particular a reasonably optimal IPAP cannot be easily determined from the results of a previous CPAP titration. Of course, setting EPAP to the CPAP level determined from a previous titration will prevent obstruction, but will yield an IPAP significantly above that CPAP level. Under these circumstances, the bilevel ventilator will perform some of the work of breathing, but deliver pressures significantly above those actually required.

Hence a method which provides expiratory pressure relief, removes the possibility of runaway pressure falls during expiration, and ensures that the pressure during inspiration is sufficient to prevent airway collapse, with the parameters determining the pressure level (if not set automatically) being based on the results of a previous CPAP titration, is desirable. This disclosure describes such a method.

Description of the invention

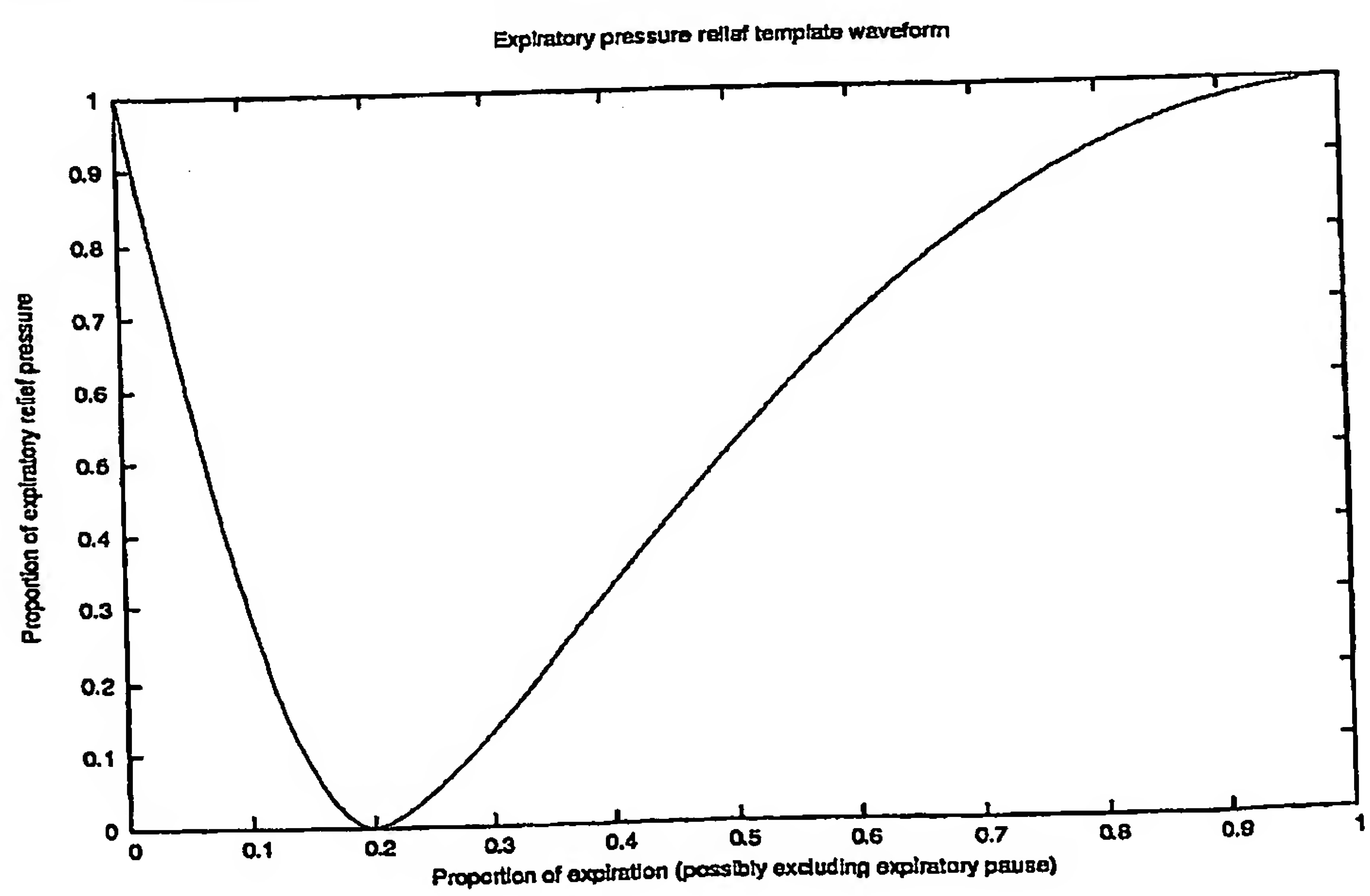
For each breath, an inspiratory pressure is determined, being either a fixed value set by a clinician or a value calculated by an automatic method (such as an AutoCPAP algorithm, e.g. the ResMed AUTOSET® algorithm (see for example WO 98/12965 or US Patent 6,575,163)). During inspiration, the pressure remains at this level (IPAP). When expiration is detected, the pressure is lowered rapidly, by an amount (the "expiratory relief pressure" (ERP)) either fixed or determined by an automatic method, but in any case by an amount not dependent on instantaneous respiratory flow. Pressure is then raised typically more slowly during the rest of expiration, in a manner intended to cause the pressure to reach the determined inspiratory level at or shortly before the end of expiration, or at the onset of the expiratory pause if any.

The ERP may determined automatically as a function of the IPAP, which is an increasing function (but not necessarily strictly increasing). For example,

$$P_{ERP}(P_{IPAP}) = \begin{cases} 0 & \text{if } P_{IPAP} \leq 4 \\ \dfrac{(P_{IPAP}-4)}{12-4} P_{ERP,\max}, & \text{if } 4 < P_{IPAP} < 12 \\ P_{ERP,\max} & \text{otherwise} \end{cases}$$

where the units of pressure are cm H_2O, and a typical value of $P_{ERP,\max}$ might be 3 cm H_2O. One reason to keep the ERP low at low IPAP is to keep expiratory pressure high enough to ensure adequate mask vent flow. Another is that less expiratory pressure relief is required at lower pressures because the additional work of breathing presented by the CPAP is less.

One method of calculating the instantaneous pressure during expiration is by determining the current estimated proportion of expiration and calculating from this the proportion of expiratory relief pressure to be delivered, using a function R of general appearance as follows:



Then in one form of the invention the instantaneous pressure delivered during expiration is

$$P = P_{IPAP} - P_{ERP} R(\alpha)$$

where α is the current estimated proportion of expiration.

In another form of the invention the instantaneous pressure delivered during expiration is

$$P = \begin{cases} P_{IPAP} - P_{ERP} R(\beta) & \text{before the expiratory pause} \\ P_{IPAP} & \text{during the expiratory pause} \end{cases}$$

where β is the current estimated proportion of the non-expiratory-pause part of the breath.

Estimating proportion of expiration (α): method 1

In this method, a method based on estimated respiratory flow, for example such as is commonly used in ventilators, is used to determine the start of inspiration and the start of expiration. From this information the duration of expiration $T_{\exp}$ can be calculated.

Low-pass filtering a time series of expiratory durations yields a typical expiratory duration $T_{\exp,LPF}$. One form of low-pass filter which may be used is the discrete-time 1st-order IIR filter with the filter update for breath number m being

$$T_{\exp,LPF,m} = kT_{\exp,m} + (1-k)T_{\exp,LPF,m-1}$$

where typical values of k are between 0.1 and 0.2.

An alternative is a median filter with a length of preferably between 5 and 7 elements, which has the advantage of rejecting outliers better than a linear low-pass filter.

The estimated current proportion of expiration is then calculated from the current time into expiration $t_{\exp}$ by

$$\alpha = \frac{t_{\exp}}{T_{\exp,LPF}}$$

Estimating proportion of non-expiratory-pause part of expiration (β): method 1

Determination of the time of the start of expiratory pause.

A variety of methods may be used; two are described here.

Method 1: The start of the expiratory pause is when the estimated flow during expiration first exceeds a small negative value such as –0.07 l/sec. (Throughout this disclosure expiratory flow is taken to be negative.) It is desirable to perform this calculation using low-pass-filtered flow with a low –3dB point, such as 5 Hz, in order better to reject artefacts. Allowance needs to be made for the delay caused by such a filter. Since the analysis can be retrospective for each breath, in which case the entire expiratory flow waveform and part of the inspiratory flow waveforms before and after

it are available, a time-symmetrical FIR filter (or the equivalent of delaying the waveform used for determination of the start of expiration by the same amount) may be used to avoid a delay between the two signals.

Method 2: The entire expiratory waveform, possibly low-pass-filtered as in method 1, is examined starting from the end of expiration and proceeding back in time. The expiratory pause is the longest contiguous period ending at the end of expiration such that the respiratory flow during that period does not lie outside a range of values which represents "small" flow, e.g. the interval –0.07 to +0.07 l/sec. The flow may be small positive and yet be part of the expiratory pause most notably because of cardiogenic airflow, or because of other artefacts not related to respiratory effort.

Determination of typical non-pause-expiration duration $T_{\exp,np,LPF}$.

Method 1

Either method 1 or method 2 for the determination of the time of the start of expiratory pause (described above) is used.

As in method 1 for α above, estimated respiratory flow is used to determine the start of expiration.

The duration of non-pause-expiration (i.e. non-expiratory-pause part of expiration) $T_{\exp,np}$ is simply the difference between the time of the start of the expiratory pause and the time of the start of that expiration. As in the determination of typical expiratory duration above, low-pass filtering a time series of non-pause-expiration durations yields a typical non-pause-expiration duration $T_{\exp,np,LPF}$.

Method 2

This is a method employing fuzzy logic (see for example US Patent 6,484,719). The membership function for the fuzzy logical quantity "small flow" is 0 for absolute values of respiratory flow greater than a value such as 0.15 l/sec and is 1 for absolute values of flow less than a smaller value such as 0.05 l/sec, with linearly interpolated values in between. The "expiratory pause" fuzzy quantity is the fuzzy AND of "small flow" and $T_{\exp} > 0.2$ sec (because we want to ignore small negative flows in early expiration; these cannot be part of the expiratory pause). The expiratory pause fraction $F_{\exp,p,LPF}$ is the low-pass-filtered value of the "expiratory pause" fuzzy logical quantity, where this filter is updated only during expiration and has a time constant of 16 seconds. We calculate $T_{\exp,LPF}$ as described above under the heading "Estimating proportion of expiration (α): method 1" and then calculate

$$T_{\exp,np,LPF} = \left(1 - F_{\exp,p,LPF}\right) T_{\exp,LPF}$$

Because this is a fuzzy method, the flow need not be as vigorously low-pass-filtered as in the first method in order to perform satisfactorily when there are artefacts in the flow signal.

Determination of β

We calculate $T_{\exp,np,LPF}$ by one of the methods described above.

As before, during expiration let time since the beginning of expiration be t_{exp}. Then if

$$t_{exp} \geq T_{exp,np,LPF}$$

we are in the expiratory pause; otherwise

$$\beta = \frac{t_{exp}}{T_{exp,np,LPF}}$$

Dealing with atypical breaths

The methods described above are based on the time into the current expiration and do not instantaneously depend on the current respiratory flow, except that respiratory flow is used to detect the start of inspiration. When breaths are typical (i.e. like the last several breaths) this method works well, particularly if the expiratory pause method is used and there is an expiratory pause, because if an expiration is shorter than usual, this often occurs at the expense of the expiratory pause, and the pressure (in an ideal mechanical implementation) has already reached IPAP by the start of the expiratory pause. However on occasion an atypically short expiration may result in the pressure being well under IPAP by the end of the breath. In order to prevent this, an additional overriding algorithm may be used to deal with atypically short expirations. In this method, if the flow during expiration reaches a small negative threshold value such as –0.15 l/sec when the calculated α or β is such that a more negative value of flow was expected, e.g. if $\beta < 0.6$, then the pressure is ramped rapidly up to IPAP, for example over a time of $0.2\, T_{exp,np,LPF}$.

Estimating proportion of expiration (α) and proportion of non-expiratory-pause part of expiration (β): method 3

In the commonly owned US Patent 6,484,719, a method for the determination of respiratory phase ϕ is described, using fuzzy logic.

The angles associated with the expiratory fuzzy logical rules given in the table in column 21 of that patent are dependent on a factor k. In that patent, k is the ratio of the standard inspiratory to the standard expiratory times. In the preferred implementation in this patent, k is an estimate of the proportion of time during expiration which is not the expiratory pause; using the definitions give above, it could be calculated by

$$k = \frac{T_{exp,np,LPF}}{T_{exp,LPF}}$$

In the preferred implementation,

$$k = 1 - F_{exp\,pause}$$

where the expiratory pause fraction $F_{exp\,pause}$ is the low-pass-filtered value of the fuzzy logical quantity EXP PAUSE, the filter having the property that it is updated only during expiration. For example, if EXP PAUSE is 1 during 0.25 of expiration and 0

during the rest of expiration, the mean value of $F_{exp\,pause}$ is 0.25. If EXP PAUSE is 1 during 0.1 of expiration, 0.5 during 0.3 of expiration, and 0 during the rest of expiration, its mean value is also 0.25. In the preferred implementation, the expiratory pause fraction low-pass filter is a first order low-pass filter with a time constant of 4 times the long-term average of the respiratory period.

More fuzzy logical rules may be added to those described in US Patent 6,484,719 to provide smoother and more reliable phase detection. In particular the preferred implementation contains 2 additional expiratory rules:

EARLY MID EXP = flow is decreasing AND flow is large negative

LATE MID EXP rules = flow is increasing AND flow is large negative

The angles associated with these rules are adjusted during algorithm refinement (but not during operation of the invention), by iteratively increasing or decreasing them, in order to give a rate of change of phase during expiration as nearly constant as possible.

It will be appreciated that these modifications of US Patent 6,484,719 are useful for the purposes contemplated in that patent as well as the purposes contemplated in the present patent.

Given ϕ as calculated by the fuzzy phase algorithm, it is straightforward to calculate

$$\beta_P = \frac{2(\phi - 0.5) - F_{exp\,pause}}{1 - F_{exp\,pause}}$$

then if $\beta_P < 0$ we are in inspiration, if $\beta_P \geq 1$ we are in the expiratory pause, else

$$\beta = \beta_P$$

Another way of looking at the combination of this method of calculating β and the method for determining desired pressure based on β given above, is that it is equivalent to the method described in US Patent 6,484,719 with a different template pressure function $\Pi(\phi)$, namely a function which is 1 for inspiratory phase, and of the general form of the expiratory pressure relief waveform given above for expiratory phase, with the minor change being that the template does not determine pressure during the expiratory pause, but a quantity equal to

$$\Pi\left(0.5 + \frac{\beta}{2}\right)$$

is used in the calculation of pressure during the non-expiratory pause part of expiration, and that the value 1 is used for Π during the expiratory pause.

The fuzzy phase rules in US Patent 6,484,719 depend on a target ventilation. This target ventilation is calculated as the low-pass-filtered observed ventilation, using a first-order filter with a time constant on the order of 1 minute, though longer and shorter time constants work reasonably well. The system is initialised with a target ventilation of 3 l/min to ensure that it is not overly prescriptive initially. Since the system described in that patent was intended to deal with hypopnoea by delivering

pressure support in a prescriptive manner, tending to ignore the patient to the extent that the patient was apnoeic, and the current invention has no such requirement, the rules can be modified in an obvious way to diminish or remove altogether their dependence on hypopnoea or hyperpnoea.

In this method for determining β, pressure depends on instantaneous flow because breath phase depends on instantaneous flow, and is capable of responding appropriately to unusually short expiratory times. Hence the method described above under the heading "Dealing with atypical breaths", intended for situations where instantaneously β depends only on time into the current expiration, is here neither necessary nor appropriate.

Compensation for slow response of the pressure delivery system

Particularly in less expensive mechanical systems for the delivery of pressure, there may be marked delays between a pressure being requested by a control system and that pressure being delivered, due for example to relatively high moments of inertia of the motor and fan. After the initial detection of expiration, and provided the fuzzy phase determination system is not being used, the requested pressure is only a function of time (except for the system used to deal with atypical breaths described above). Hence the desired pressure in the near future is known, and so it is possible to compensate for an expected delay by requesting pressures in advance by an amount equal to the expected delay. This is an advantage of the present invention over systems which respond to instantaneous flow.

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